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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,062

07/30/2006

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MAGERL1

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1444 7590 10/30/2007  
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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

4123

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/554,062

Applicant(s)

MAGERL ET AL.

Examiner

Jan Christopher Merene

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/24/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This is the initial Office action based on the 10/544,062 application filed on July 30, 2006, which is a 371 of PCT/CH04/00244 filed on September 22, 2004. Claims 1-17, as originally filed, are currently pending and have been considered below. Claim 1 is independent.

#### ***Drawings***

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because a) the lines, numbers and letters are not uniform, clean and well defined (of a generally poor quality) in Figures 10-15 (37 CFR 1.84(l)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

#### ***Specification***

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-8 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Rogozinski 5,607,425.

Regarding **Claim 1**, Rogozinski discloses a device for spondylodesis and in particular for anterior intersomatic spondylodesis of the cervical spine, with at least one intervertebral implant and with at least one plate (link #220) which is to be connected to the intervertebral implant and to an adjacent vertebra, characterized in that the intervertebral implant is connected to at least two plates (links #220 and #240) which are arranged at a distance from one another, one end of each of the two plates forming a fixable joint together with the intervertebral implant (see Col 5 lines 8-19, where constructs #210 and #230 form a plurality of links #220 and #240, with securing means in the form of screws, bolts or hook members, as seen in Fig 5.)

Regarding **Claim 2**, Rogozinski discloses a device, characterized in that at least one of the plates has a Z-shaped, I-shaped or L- shaped configuration (see Fig 5, link #240 as being I-shaped).

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Regarding **Claim 3**, Rogozinski discloses a device, where one plate, in a central area extending transversely with respect to the longitudinal axis of the spinal column, has at least one passage for a bone screw, so that this plate can be connected to a vertebra (see Col 5 lines 8-19, where constructs #210 and #230 form a plurality of links #220 and #240, with securing means in the form of screws, bolts or hook members, as seen in Fig 5).

Regarding **Claim 4**, Rogozinski discloses a device, characterized in that said area has two passages (#222) arranged at a distance from one another and each intended for a bone screw (see Col 5 lines 8-19, where securing means in the form of screws, bolts or hook members, as seen in Fig 5.)

Regarding **Claim 5**, Rogozinski discloses a device, characterized in that at least one plate (link #310) has, at least at one end, a hemispherical and protruding joint part (bolt #150 and nut #170) which has a passage for a locking screw (bolt #50) and which engages in a hemispherical depression of an intervertebral implant in such a way that a ball joint is formed (bolt #150 and nut #170).

Regarding **Claim 6**, Rogozinski discloses a device, characterized in that at least two plates (links #410) are each connected to an intervertebral implant, in particular a ball joint (see Fig 7, where links #410 are connected to each other via bolts or hooks and locking nuts #470).

Regarding **Claim 7**, Rogozinski discloses a device, characterized in that at least two L-shaped plates are connected to an intervertebral implant (see Fig 4, where L-shaped implants, links #10 are connected together).

Regarding **Claim 8**, Rogozinski discloses a device, characterized in that the two plates (link #10) each having, in extending transversely with respect to the longitudinal direction of the spinal column (ends #12 and #14), at least two passages (apertures #18) which are arranged at a distance from one another and each receive a bone screw (see Col 4 lines 28-31 and Fig 1a, link #10, with apertures #18 on ends #12 and #14, configured to receive a bone screw).

Regarding **Claim 12**, Rogozonski discloses the device, characterized in that it is provided for spondylodesis of the cervical spine (see Col 1 lines 16-23, wherein the invention relates generally to apparatus and methods for treating and correcting spinal abnormalities or conditions, stabilizing the position of the spine and vertebrae thereof).

6. **Claims 1-2** are rejected under 35 U.S.C. 102(b) as being anticipated by Karpf 5,000,166.

Regarding **Claim 1**, Karpf discloses a device for spondylodesis and in particular for anterior intersomatic spondylodesis of the cervical spine, with at least one intervertebral implant (stabilizing element #2) and with at least one plate (bands #1) which is to be connected to the intervertebral implant and to an adjacent vertebra,

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characterized in that the intervertebral implant is connected to at least two plates (see Figs 3 and 4 to see stabilizing element #2 and bands #1 connected) which are arranged at a distance from one another, one end of each of the two plates forming a fixable joint together with the intervertebral implant (see Figs 3 and 4 to see stabilizing element #2 and bands #1 connected to each other via screws #9, thus forming a fixable joint).

Regarding **Claim 2**, Karpf discloses a device, characterized in that at least one of the plates has a Z-shaped, I-shaped or L- shaped configuration (see Fig 2, band #1 is I shaped).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 9 and 10** Are rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 in view of Zucherman et al 5,836,948.

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Rogozinski discloses the claimed invention of intervertebral implants (links #10) connected to each other, thus forming Z-shaped plates (refer to Fig 4, wherein links #10 form a Z-shaped plate connect to other L-shaped plates) and all the connections between the plates and the intervertebral implants being designed as polyaxial joints, in particular ball joints (see Col 4 lines 28-31 and Figs 1a and 4, link #10, with apertures #18 on ends #12 and #14, configured to receive a bone screw).

Rogozinski does not appear to explicitly disclose a Z-shaped plate comprising of one piece.

However, Zucherman et al discloses an intervertebral implant that is Z-shaped (see Figs 69-71).

Rogozinski and Zucherman are analogous art because they are from the same field of endeavor area of spinal implants.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Rogozinski and Zucherman before him or her to modify the links #10 of Rogozinski to be integral, thus being Z-shaped of Zucherman because being Z-shaped allows for implant the device between the two spinous processes (lines Col 15 lines 5-13).

The suggestion/motivation for doing so would have been being Z-shaped allows for implant the device between the two spinous processes (lines Col 15 lines 5-13).

Therefore, it would have been obvious to combine Rogozinski with Zucherman to obtain the invention in the instant claims.



10. **Claim 11** is rejected under 35 U.S.C. 103(a) as being obvious over Rogozinski 6,336,927 in view of Lawson 6,074,423.

Rogozinski discloses the claimed device but does not appear to explicitly disclose at least one plate and/or an intervertebral implant is/are made of a material transparent to X- rays.

However, Lawson discloses an intervertebral implant that made of a material transparent to X- rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

Rogozinski and Lawson are analogous art because they are from the same field of endeavor of spinal implants.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Rogozinski and Lawson before him or her to modify the implant of Rogozinski to include the transparent x-ray material of Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

The motivation for doing so would have been obvious because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

Therefore, it would have been obvious to combine Rogozinski with Lawson to obtain the invention in the instant claim.

11. **Claims 13-14, and 16** rejected under 35 U.S.C. 103(a) as being obvious over Karpf 5,000,166 in view of Zucherman 5,836,948.

Regarding **Claim 13**, Karpf discloses a kit for producing the device as claimed in claim 1, with at least one intervertebral implant (stabilizing element #2) and with at least one plate for connecting the intervertebral implant to at least one vertebra (bands #1) as seen in Fig 3), characterized in that at least one plate is L-shaped, with the plates connected to each other to form a Z-shaped pattern (band #14 with tabs #13 having a L and Z shape configuration), and in that at least one intervertebral implant has two bores (bores #5 and #8) and which are arranged at a distance from one another and each receive a locking screw (screw #9).

However, Karpf does not appear to explicitly disclose a single Z-shaped plate comprising of one piece.

However, Zucherman et al discloses an intervertebral implant that is Z-shaped (see Figs 69-71).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Karpf and Zucherman before him or her to modify the bands #1 and #14 of Karpf to be integral, thus being Z-shaped of Zucherman because

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being Z-shaped allows for implant the device between the two spinous processes (lines Col 15 lines 5-13).

The suggestion/motivation for doing so would have been being Z-shaped allows for implant the device between the two spinous processes (lines Col 15 lines 5-13).

Therefore, it would have been obvious to combine Karpf with Zucherman to obtain the invention in the instant claims.

Regarding **Claim 14**, Karpf discloses a kit, characterized in that the intervertebral implant and the plates each have at least one joint part for forming a ball joint (see Fig 3, where bands #1 and stabilizing element #2 have apertures #5 and #8 have screws #9 going through them).

Regarding **Claim 16**, Karpf discloses a kit characterized by a plurality of bone screws and a plurality of locking screws (refer to Fig 3, where screws #9 are used).

12. **Claim 15** is rejected under 35 U.S.C. 103(a) as being obvious over Karpf 5,000,166 in view of Zucherman 5,836,948 as applied to claim 13 above, and further in view of Lawson 6,074,423.

Karpf discloses the claimed invention except the intervertebral implant and the plates are made of a material transparent to X-rays.

However, Lawson discloses an intervertebral implant that made of a material transparent to X-rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is

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made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

Karpf and Lawson are analogous art because they are from the same field of endeavor of spinal implants.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Karpf and Lawson before him or her to modify the implant of Karpf to include the transparent x-ray material of Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

The motivation for doing so would have been obvious because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

Therefore, it would have been obvious to combine Karpf with Lawson to obtain the invention in the instant claim.

13. **Claim 17** is rejected under 35 U.S.C. 103(a) as being obvious over Karpf 5,000,166 in view of Zucherman 5,836,948 as applied to claim 16 above, and further in view of Mast 5,269,784.

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Karpf discloses the claimed invention as claimed above except locking screws that are ball-head screws having a screw head, which is substantially hemispherical on its underside.

However, Mast teaches locking screws that are ball-head screws having a screw head, which is substantially hemispherical on its underside (screw #15 and bushing #12 as seen in Fig 7).

Karpf and Mast are analogous art because they are from the same field of endeavor of bone implants.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Karpf and Mast before him or her to modify the screw #9 of Karpf to include the screw #15 and bushing #12 of Mast because it has universal applicability since it can be used together with any type of bone plates and screws and may be used selectively at single positions of the bone plate, respectively with single bone screws inserted therein (see Col 3 lines 9-16).

The suggestion/motivation for doing so would have been obvious because the screw #15 and bushing #12 of Mast has universal applicability since it can be used together with any type of bone plates and screws and may be used selectively at single positions of the bone plate, respectively with single bone screws inserted therein (see Col 3 lines 9-16).

Therefore, it would have been obvious to combine Mast with Karpf to obtain the invention in the instant claim.

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### Conclusion

Please refer to Form 892, where the examiner notes references not used in this office action but are considered pertinent art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan Christopher Merene whose telephone number is 571-270-5032. The examiner can normally be reached on Mon-Thurs 7:30 am -6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Solé can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCM

  
JOSEPH DEL SOLE  
SUPERVISORY PATENT EXAMINER

10/30/07